IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATE TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9534

Bartle, J. November 18, 2021

The Estate of Alice C. Petersen ("Estate", a representative class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD").

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To seek Matrix Benefits, a representative claimant[3] must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In June, 2019, the Estate submitted a completed Green Form to the Trust signed by the attesting physician, Michael Mancina, M.D., F.A.C.C. Based on an echocardiogram dated March 11, 2000, Dr. Mancina attested in Part II of the Green Form that Ms. Petersen suffered from mid aortic regurgitation,

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See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs, or beneficiaries. See Settlement Agreement § II.B.

moderate mitral regurgitation, mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation with bacterial endocarditis,[4] an abnormal left atrial dimension, and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

In February, 2020, the Estate submitted an amended Part II of the Green Form in which Dr. Mancina attested that Ms. Petersen also suffered death as a result of a condition caused by VHD or valvular report/replacement surgery.[5] Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits,[6] in the gross amount of $1,510,758.[7]

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4. Dr. Mancina later explained that this response was mismarked and that Ms. Petersen did not suffer from bacterial endocarditis. This condition is therefore not at issue in this claim.

5. As required by the Green Form, the Estate included a statement of Ms. Petersen's attending board-certified cardiologist, Ghiyath Tabbal, M.D., F.H.R.S., setting forth his opinion that Ms. Petersen's death resulted from a condition caused by VHD and/or valvular repair/replacement surgery.

6. Under the Settlement Agreement, a claimant is entitled to Level V benefits if, among other things, (1) the Diet Drug Recipient suffers death resulting from a condition caused by VHD or valvular repair/replacement surgery, see Settlement Agreement § IV.B.2.c.(5)(c); or (2) the Diet Drug Recipient qualifies for Level II benefits and suffers from ventricular fibrillation or sustained tachycardia which result in hemodynamic compromise, see id. § IV.B.2.c.(5)(d). A claimant is entitled to Level II benefits for damage to the mitral valve if the Diet Drug Recipient is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement, including an abnormal left atrial

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In the report of Ms. Petersen's echocardiogram, the reviewing cardiologist, Lawrence S. Cohen, M.D., stated that claimant had "mild mitral regurgitation with 28% regurgitant jet area/left atrial area ratio." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2019, the Trust forwarded the claim for review by Zuyue Wang, M.D., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for finding that claimant had moderate mitral regurgitation. In April, 2020, the Trust forwarded the amended claim for review by Dr. Wang. In audit, Dr. Wang concluded that there was no reasonable medical basis for finding that

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dimension. See id. § IV.B.2.c.(2)(b)ii). As the Trust does not contest that Ms. Petersen had an abnormal left atrial dimension or that she suffered from ventricular fibrillation or sustained tachycardia which result in hemodynamic compromise, the only conditions at issue in this claim are the level of her mitral regurgitation and whether she suffered death as a result of a condition caused by VHD or valvular repair/replacement surgery.

7. Because Ms. Petersen previously was paid Matrix A-1, Level II benefits, if the Estate is entitled to A-1, Level V benefits, it only would be entitled to the difference between the Matrix A-1, Level II benefits already paid and the amount of Matrix A-1, Level V benefits.

Ms. Petersen suffered death resulting from a condition caused by VHD or valvular repair/replacement surgery. Dr. Wang explained,

> The death was not caused by [VHD] because the echo on 8/1/17 prior to death showed normal left ventricular size, normal systolic/diastolic function, normal right ventricular function, only mild mitral regurgitation, no aortic regurgitation and no pulmonary hypertension. There was no evidence of structural and hemodynamic impact from mild mitral regurgitation. Mild mitral regurgitation and/or aortic regurgitation does not cause atrial and ventricular fibrillation. Long-standing SEVERE mitral and/or aortic regurgitation can potentially cause left ventricular (LV) dilation and dysfunction, which subsequently results in ventricular or atrial fibrillation. [Patient] had mild mild [sic] regurgitation and normal LV size and function.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination that the Estate was not entitled to Matrix A-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, the Estate argued that there was a reasonable basis for finding that

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

Ms. Petersen suffered moderate mitral regurgitation. In support, the Estate submitted a statement from Dr. Mancina in which he said, "Three well defined mitral regurgitant jets are seen originating from the mitral leaflet that have an RJA exceeding twenty percent." Dr. Mancina included pictures of the three jets as further support. In addition, the Estate argued that there was a reasonable basis for finding that Ms. Petersen suffered death as a result of a condition caused by VHD or valvular repair/replacement surgery. In support, the Estate submitted a statement by Dr. Tabbal in which he said that the auditing cardiologist's definition was too narrow and failed to take into consideration "individual bio-variability." Dr. Tabbal included several medical journals and abstracts in support of his position. Dr. Tabbal also explained that he ruled out other causes of Ms. Petersen's arrhythmias.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Wang submitted a declaration in which she again concluded that there was no reasonable medical basis for finding that Ms. Petersen had moderate mitral regurgitation or that she suffered death as a result of a condition caused by VHD or valvular repair/replacement surgery. Specifically, Dr. Wang stated:

> 11. As requested by the Trust, I again reviewed the Claim as well as Claimant's Contest Materials.
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> 12. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had moderate mitral regurgitation. Upon review in contest, I again reviewed the entire March 11, 2000 [echocardiogram of attestation], identified a regurgitant jet representative of the mitral regurgitation seen in real time. The mitral valve regurgitation is clearly only mild with an RJA/LAA ratio clearly less than the 20% threshold to find moderate mitral regurgitation. I also confirm my findings that Ms. Peterson's [sic] left ventricular size was normal with supernormal EF of 74% and confirm my opinion that her mild mitral and aortic regurgitation was not the cause for the ventricular tachycardia which resulted in her death.
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> 13. This patient presented to the Emergency Room two days after atrial flutter ablation with complaints of shortness of breath. No echocardiogram was performed at that time and she was treated for hypervolemia with diuretics. She returned to the ER three weeks later, on August 21, 2017 with hypotension/ventricular tachycardia (VT) and passed away after cardioversion for VT. There was no sign of CHF based on the chest X-ray and ER note of August 21,2017.

The Trust then issued a final post-audit determination again determining that the Estate was not entitled to Matrix A-1, Level V benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement

Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On April 20, 2021, the court issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9531 (Apr. 20, 2021).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 16, 2021. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Advisor Report are now before the court for final determination. See id. Rule 35.

The issues presented for resolution of this claim are whether claimant has met its burden of proving that there is a reasonable medical basis for finding that Ms. Petersen had moderate mitral regurgitation and that Ms. Petersen suffered death as a result of a condition caused by VHD or valvular report/replacement surgery. See id. Rule 24. Ultimately, if there is no reasonable medical basis for either of these findings, the court must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, there is a reasonable medical basis for one of these findings, the court must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, the Estate repeats the arguments that it made in contest. In addition, the Estate contends that the reasonable medical basis standard "is not a competition between different medical diagnoses, but rather, is a relatively liberal standard where differing medical opinions may all fall within the scope of a reasonable medical basis." Claimant contends that Dr. Tabbal's statement "is truly relevant here," because whether Ms. Petersen died as a result of a condition caused by VHD or valvular report/replacement surgery

"requires a clinical, 'hands on' diagnosis of those underlying medical factors that contributed to the condition that resulted in death."

In response, the Trust argues that the Settlement Agreement requires denial of the claim because the auditing cardiologist determined that there was no reasonable medical basis for the Green Form representations at issue. According to the Trust, claimant's attesting and attending physicians are not entitled to deference. With respect to the level of Ms. Petersen's mitral regurgitation, the Trust notes that the echocardiogram improperly includes low velocity flow as mitral regurgitation. With respect to whether Ms. Petersen died as a result of a condition caused by VHD or valvular report/replacement surgery, the Trust maintains that the Estate fails in its proof. While the Estate disputed the "generalization that mild mitral regurgitation and/or aortic regurgitation does not cause atrial and ventricular fibrillation," it did not dispute the auditing cardiologist's specific findings that: (1) Ms. Petersen's August 1, 2017 echocardiogram showed normal left ventricular size, systolic/diastolic function, and right ventricular function and did not show any aortic regurgitation or pulmonary hypertension; (2) there was no evidence of any structural or hemodynamic impact from Ms. Petersen's mitral regurgitation; and

(3) Ms. Petersen died after cardioversion for ventricular tachycardia with no sign of congestive heart failure on the chest x-ray or emergency department note of August 21, 2017.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram. He concluded that there was no reasonable medical basis for finding that Ms. Petersen had moderate mitral regurgitation or that she died as a result of a condition caused by VHD or valvular report/replacement surgery. Specifically, Dr. Vigilante stated, in pertinent part:

> I reviewed the DVD and multiple VHS tapes of the March 11, 2000 echocardiogram. These were all copies of the same study. In addition, the name "Michael S. Mancina, MD" was noted over the top of the study. The usual echocardiographic views were obtained. This was a below quality study as it was quite grainy and there was difficult endocardial definition presumable due to the claimant's morbid obesity. However, the study was diagnostic in evaluation of the issue in the parasternal long-axis, apical four chamber, and apical two chamber views. The Nyquist limit was appropriately set at 64.1 cm per second at a depth of 23.1 cm in the parasternal long axis view as well as 67.3 cm per second at a depth of 20.1 cm in the apical four chamber view and 64.1 cm per second at a depth of 23.1 in the apical two chamber view. However, there was excessive color gain with color artifact noted outside the cardiac chambers. . . . I digitized the cardiac cycles in the apical four chamber view in which the mitral regurgitant jet appeared most impressive. I then measured the RJA and LAA by electronic calipers. I determined that the largest representative RJA was 2.3 cm2. The LAA was 19.8 cm2.

Therefore, the largest representative RJA/LAA ratio was 12% diagnostic of mild mitral regurgitation. The ratio did not come close to approaching the ratio of 20%. The sonographer-measured RJA of 4.45 cm2 was grossly inaccurate as it included low velocity and non-regurgitant flow. In addition, the sonographer-measured LAA was inaccurately small as it is an off axis view of the left atrium. Indeed, the left atrium was dilated and the sonographer measurement of the LAA of 15.8 cm2 is not consistent with the left atrial enlargement. It should be noted that the RJA was even smaller in the apical two chamber view.

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In response to Question 1, there is no reasonable medical basis for the Attesting Physician's representation that Claimant's March 11, 2000 echocardiogram demonstrated moderate mitral regurgitation. Without question, the echocardiogram demonstrated mild mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

In response to Question 2, there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question L.4., which states that the Diet Drug Recipient suffered death resulting from a condition caused by [VHD] or valvular repair/replacement surgery. That is, this patient had, at most, mild mitral regurgitation and mild aortic regurgitation on multiple echocardiograms including the transesophageal echocardiogram from October 8, 2015 and the echocardiogram of August 1,2017 which I reviewed. The last study occurred only 20 days prior to her death. The Diet Drug Recipient had never been clinically diagnosed with any worse than mild mitral regurgitation and mild aortic

> insufficiency. There is no chance that these mild valvular abnormalities caused the Diet Drug Recipient's death. Instead, it is obvious that her death occurred from an uncontrollable and malignant ventricular arrhythmia that was not related to her mild valvular condition. This malignant arrhythmia could be considered a complication of her electrophysiologic procedure that occurred less than one month prior to her death. In addition, her malignant arrhythmia was related to pulmonary hypertension, significantly dilated right sided cardiac chambers, obstructive sleep apnea, hypertension, and morbid obesity.

After reviewing the entire show cause record, the court finds that the Estate has not established a reasonable medical basis for its claim. Claimant does not adequately refute the findings of the auditing cardiologist and Technical Advisor that there is no reasonable medical basis for the representation that Ms. Petersen's echocardiogram demonstrates moderate mitral regurgitation. As the court previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation;

(7) failing to take a claimant's medical history; and

(8) overtracing the amount of a claimant's regurgitation.

See Mem. in Supp. of PTO No. 2640 at 9–13, 15, 21–22, 26 (Nov. 14, 2002).

Dr. Wang and Dr. Vigilante each determined that the echocardiogram demonstrated only mild mitral regurgitation. Although claimant's attesting physician submitted three images from the echocardiogram that he claimed demonstrated moderate mitral regurgitation, Dr. Wang determined that the "RJA encircled on the study includes low velocity flow, falsely inflating the RJA/LAA ratio." Similarly, Dr. Vigilante concluded that "there was excessive color gain with color artifact noted outside the cardiac chambers" and that "[t]he sonographer-measured RJA of 4.45 cm2 was grossly inaccurate as it included low velocity and non-regurgitant flow."

Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis of mild aortic regurgitation. To conclude otherwise would allow claimants who do not have moderate mitral regurgitation to receive Matrix Benefits. Such a result would be contrary to the intent of the Settlement Agreement.

Furthermore, claimant does not adequately refute the findings of the auditing cardiologist and Technical Advisor that there is no reasonable medical basis for representing that

Ms. Petersen died as a result of a condition caused by VHD or valvular report/replacement surgery. Dr. Wang determined that Ms. Petersen's death was not caused by VHD. He explained that the echocardiogram taken immediately prior to her death "showed normal left ventricular size, normal systolic/diastolic function, normal right ventricular function, only mild mitral regurgitation, no aortic regurgitation and no pulmonary hypertension, . . . [and] no evidence of structural and hemodynamic impact from mild mitral regurgitation." She also noted that mild mitral regurgitation and/or aortic regurgitation does not cause atrial and ventricular fibrillation and that Ms. Petersen did not have the long-standing severe regurgitation that would cause left ventricular dilation and dysfunction.

Similarly, Dr. Vigilante similarly observed that Ms. Petersen was never clinically diagnosed with more than mild mitral regurgitation, which could not have caused her death. Dr. Vigilante concluded that "her death occurred from an uncontrollable and malignant ventricular arrhythmia that was not related to her mild valvular condition."

Dr. Tabbal, Ms. Petersen's attending physician, did not address Dr. Wang's specific findings that: Ms. Petersen had a normal left ventricular size, systolic/diastolic function, and right ventricular function; did not have any aortic regurgitation or pulmonary hypertension or evidence of any

structural or hemodynamic impact from her mitral regurgitation; or that she died after cardioversion for ventricular tachycardia with no sign of congestive heart failure.

Rather, Dr. Tabbal agreed that arrhythmias are more commonly associated with severe levels of regurgitation but provided one medical journal article and two abstracts that he contended support his conclusion that mild regurgitation can contribute to arrhythmias. However, Dr. Vigilante, after review of these documents, explained that they related either to patient populations or disease conditions that were not relevant to Ms. Petersen and therefore did not support Dr. Tabbal's conclusion.

Claimant also argued that the reasonable medical basis standard "is a relatively liberal standard where differing medical opinions may fall within the scope of a reasonable medical basis." The court disagrees with claimant's interpretation of the reasonable medical basis standard. The standard delineated in the Settlement Agreement and Audit Rules must be applied. It requires a "reasonable medical basis" that is more stringent than claimant contends. When, as here, claimant and the attending physician fail to address the auditing cardiologist's specific findings, claimant fails to satisfy the reasonable medical basis. See In re Diet Drugs (Phentermine/Fenfluramine/ Dexfenfluramine) Prods. Liab. Litig.

(Venetz), 601 F. App'x 143, 147 (3d Cir. 2015) (citing In re Diet Drugs (Phentermine/ Fenfluramine/Dexfenfluramine) Prods. Liab. Litig. (Patterson), 543 F.3d 179, 190 (3d Cir. 2008)).

For the foregoing reasons, the court concludes that the Estate has not met its burden of proving that there is a reasonable medical basis for finding that Ms. Petersen had moderate mitral regurgitation or that she died as a result of a condition caused by VHD. Therefore, the Trust's denial of the Estate's claim for Matrix A-1, Level V benefits will be affirmed.